

REMARKS/ARGUMENTS

Claims 1-20 are active in this application.

Claims 8-13 have been withdrawn in view of the Restriction imposed by the Office. However, these withdrawn claims have been retained in this case so that Applicants can request that these claims be rejoined with the elected product claims in accordance with the guidelines set forth in MPEP 821.04.

The amendments to claims 1 and 14 are to correct minor typographical errors. No new issues or new matter is believed to have been added by these amendments. Therefore, entry is requested.

As claimed herein, the invention is directed to soybean (and their seeds) that fail to express certain subunits of  $\beta$ -conglycinin and glycinin, the result of which is a soybean line (and their seeds) that have a total free amino acid content greater than that found in seeds of conventional soybean varieties or lines. This is particularly advantageous in terms of the use of the soybean (and their seeds) in preparing functional foods high in free amino acids, the advantages of which are discussed, e.g., on pages 1-2 of the specification.

The rejections under 35 USC 112, first paragraph (written description and enablement) are respectfully traversed.

In support of Applicants position that the claims as presented herein are both described and enabled by the specification, an executed Rule 132 Declaration is attached.

The Written Description is based on the presumption that the application does not describe the genus of soybean seeds claimed, except for the specific lines described. The point is missed.

A soybean is a soybean. A common characteristic of genus/species differentiation is that they share common genetics. Therefore, soybeans as a general class would have the subunits and removing those as set forth in the specification would be readily appreciated to

be within the Applicants possession at the time of filing. Again, the invention is based, in part, on the generation of mutants in certain soybean lines as representative of soybeans in general. That the removal of the subunit or subunits would result in the properties described and defined in the claims. This fact is further exemplified by the Experiments shown in the Declaration, in which additional lines were generated lacking the subunit or subunits as claimed and having the properties identified in the specification.

The written description requirement “serves a teaching function, as a ‘*quid pro quo*’ in which the public is given ‘meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time.’” *Univ. of Rochester*, 358 F.3d at 926, 69 USPQ2d at 1891 (quoting *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 970, 63 USPQ2d 1618, 1619 (Fed. Cir. 2002)). To obtain this “quid pro quo,” the applicant must “convey to those skilled in the art that, as of the filing date sought, he or she was in possession of the *invention* . . . by describing *the invention*, with all its claimed limitations.” *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Here, the Applicants have done just this—they have identified certain subunits of  $\beta$ -conglycinin that when removed from the soybean generates a higher total free amino acid content than other seeds having different modifications.

In addition, as stated in the Declaration:

5. Additional data which are further examples of the claimed soybeans other than the soybean lines QF2F<sub>3</sub>-1, QF2F<sub>3</sub>-2, and QF2F<sub>3</sub>-3 as described in the specification. The data relate to the analysis of free amino acids in soybean seeds of Fukuyutaka BC<sub>1</sub>F<sub>5</sub> line and Jack BC<sub>1</sub>F<sub>4</sub> line.

6. Fukuyutaka BC<sub>1</sub>F<sub>5</sub> line and Jack BC<sub>1</sub>F<sub>4</sub> line were used in the analysis of free amino acids in soybean seeds.

7. The Fukuyutaka BC<sub>1</sub>F<sub>5</sub> line was produced as follows:

QF2 line (genetically lacking all subunits of  $\beta$ -conglycinin and glycinin) was produced from the cross F2 population between the Kyukei 305 (genetically lacking all subunits of  $\beta$ -conglycinin) and EnBI (genetically lacking all subunits of glycinin). Then, the obtained QF2 line was backcrossed twice with Fukuyutaka (which does not lack  $\beta$ -conglycinin or glycinin genetically) to produce the Fukuyutaka BC<sub>1</sub>F<sub>5</sub> line,

8. The Jack BC<sub>1</sub>F<sub>4</sub> line was produced as follows:

QF2 line (genetically lacking all subunits of  $\beta$ -conglycinin and glycinin) was produced from the cross F2 population between the Kyukei 305 (genetically lacking all subunits of  $\beta$ -conglycinin) and EnB1 (genetically lacking all subunits of glycinin). Then, the obtained QF2 line was backcrossed twice with Jack (which does not lack  $\beta$ -conglycinin or glycinin genetically) to produce the Jack BC<sub>1</sub>F<sub>4</sub> line.

9. The protein compositions of each seed of the Fukuyutaka BC<sub>1</sub>F<sub>4</sub> line and the Jack BC<sub>1</sub>F<sub>4</sub> line were confirmed by SDS-PAGE, then seeds were freeze-dried. The freeze-dried seeds were then subjected to mill pulverization to obtain seed flour as samples for analysis of amino acids.

10. Soluble (free) amino acids were extracted from the freeze-dried seed flour (200mg) with 1,600  $\mu$ l of 3 % sulfosalicylic acid by shaking for 60 minutes. The suspension was then centrifuged at 15,000 rpm at 18°C for 10 minutes. The obtained supernatant was filtered with a 0.45  $\mu$ m filter. The extract was then analyzed for soluble amino acids. The composition and content of free amino acids were determined with an automatic amino acid analyzer (L-8900 or L-8800; Hitachi High-technologies, Tokyo, Japan).

11. Tables 1 and 2 show the results regarding Fukuyutaka BC<sub>1</sub>F<sub>4</sub> line and Jack BC<sub>1</sub>F<sub>4</sub> line, respectively.

Table 1

Fukuyutaka BC <sub>1</sub> F <sub>5</sub> line			1	8	9	16
$\beta$ -conglycinin subunit	$\alpha$		+	+	-	-
	$\alpha'$		+	+	-	-
	$\beta$		+	+	-	-
glycinin subunit	I	A <sub>1a</sub> B <sub>2</sub> , A <sub>2</sub> B <sub>1a</sub> , A <sub>1b</sub> B <sub>1b</sub>	+	-	+	-
	IIa	A <sub>5</sub> A <sub>4</sub> B <sub>3</sub>	+	-	+	-
	IIb	A <sub>3</sub> B <sub>4</sub>	+	-	+	-
free amino acid (mg/gDW)	Asp	aspartic acid	0.462	0.626	0.768	1.388
	Glu	glutamic acid	0.284	0.343	0.327	0.990
	Ser	serine	0.012	0.020	0.033	0.024
	Asn	asparagine	0.079	0.400	0.449	3.261
	Gly	glycine	0.181	0.262	0.205	0.442
	Gln	glutamine	0.002	0.001	0.000	0.031
	His	histidine	0.015	0.053	0.046	0.179
	Thr	threonine	0.007	0.016	0.023	0.032
	Ala	alanine	0.179	0.247	0.220	0.410
	Arg	arginine	0.481	2.742	2.922	20.285
	Pro	proline	0.010	0.123	0.019	0.062
	Tyr	tyrosine	0.009	0.019	0.005	0.033
	Val	valine	0.034	0.042	0.055	0.086
	Met	methionine	0.022	0.013	0.031	0.029
	Cys	cysteine	0.000	0.000	0.000	0.000
	Ile	isoleucine	0.027	0.028	0.035	0.071
	Leu	leucine	0.036	0.020	0.049	0.044
	Phe	phenylalanine	0.046	0.037	0.055	0.049
	Trp	tryptophan	0.136	0.161	0.072	0.067
	Lys	lysine	0.052	0.067	0.086	0.196
	total		2.073	5.219	5.398	27.680

Table 2

Variety or line name			Jack	JackBC <sub>1</sub> F <sub>4</sub>
β-conglycinin	α		+	-
	subunit α'		+	-
	β		+	-
glycinin	I	A <sub>1a</sub> B <sub>2</sub> , A <sub>2</sub> B <sub>1a</sub> , A <sub>1b</sub> B <sub>1b</sub>	+	-
	subunit IIa	A <sub>5</sub> A <sub>4</sub> B <sub>3</sub>	+	-
	IIb	A <sub>3</sub> B <sub>4</sub>	+	-
free amino acid (mg/gDW)	Asp	aspartic acid	0.313	1.221
	Glu	glutamic acid	0.326	1.619
	Ser	serine	0.023	0.039
	Asn	asparagine	0.098	5.228
	Gly	glycine	0.049	0.098
	Gln	glutamine	0.002	0.000
	His	histidine	0.030	1.315
	Thr	threonine	0.018	0.058
	Ala	alanine	0.175	0.398
	Arg	arginine	0.298	15.916
	Pro	proline	0.109	0.406
	Tyr	tyrosine	0.029	0.049
	Val	valine	0.019	0.148
	Met	methionine	0.036	0.067
	Cys	cysteine	0.000	0.000
	Ile	isoleucine	0.031	0.112
	Leu	leucine	0.029	0.084
	Phe	phenylalanine	0.047	0.062
	Trp	tryptophan	0.185	0.125
	Lys	lysine	0.045	0.196
	total		1.865	27.143

12. As is clear from Tables 1 and 2, the arginine content and total free amino acid contents in the seeds of the Fukuyutaka BC<sub>1</sub>F<sub>4</sub> line and the Jack BC<sub>1</sub>F<sub>4</sub> line were increased remarkably relative to those of the conventional soybean variety (line 1 in Table 1 and the variety "Jack" in Table 2).

13. Therefore, , a person skilled in the art could have made the claimed soybeans other than the soybean lines QF2F<sub>3</sub>-1, QF2F<sub>3</sub>-2, and QF2F<sub>3</sub>-3 on the basis of the description of the specification without undue experimentation.

Withdrawal of the rejections is therefore requested.

A Notice of Allowance indicating that Claims 1-20 are allowed is also requested.

Respectfully submitted,

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MAIER & NEUSTADT, P.C.  
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IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF :  
MASAKAZU TAKAHASHI, ET AL. : EXAMINER: ROBINSON  
SERIAL NO: 10/812,916 :  
FILED: MARCH 31, 2004 : GROUP ART UNIT: 1638  
FOR: SOYBEAN CONTAINING HIGH :  
LEVELS OF FREE AMINO ACIDS :

DECLARATION UNDER 37 C.F.R. 1.132

I, MASAKAZU TAKAHASHI hereby declare:

1. I am employed by National Agriculture and Food Research Organization, National Agricultural Research Center for Kyushu Okinawa Region as a researcher and have experience in the field of soybean breeding.

2. I am familiar with the specification of the above-identified patent application.

3. The following observations and experiments were carried out by me or under my direct supervision and control.

4. The present invention is directed to a soybean genetically lacking all subunits of  $\beta$ -conglycinin, and at least one group of glycinin subunits selected from (i)  $A_{1a}B_2$ ,  $A_2B_{1a}$ ,  $A_{1b}B_{1b}$ ; (ii)  $A_5A_4B_3$ ; and (iii)  $A_3B_4$ .

5. Additional data which are further examples of the claimed soybeans other than the soybean lines QF2F<sub>3</sub>-1, QF2F<sub>3</sub>-2, and QF2F<sub>3</sub>-3 as described in the specification. The data relate to the analysis of free amino acids in soybean seeds of Fukuyutaka BC<sub>1</sub>F<sub>5</sub> line and Jack BC<sub>1</sub>F<sub>4</sub> line.

6. Fukuyutaka BC<sub>1</sub>F<sub>5</sub> line and Jack BC<sub>1</sub>F<sub>4</sub> line were used in the analysis of free amino acids in soybean seeds.

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Declaration

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	IIa	A <sub>5</sub> A <sub>4</sub> B <sub>3</sub>	+	-	+	-
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13. Therefore, a person skilled in the art could have made the claimed soybeans other than the soybean lines QF2F<sub>3</sub>-1, QF2F<sub>3</sub>-2, and QF2F<sub>3</sub>-3 on the basis of the description of the specification without undue experimentation.

14. The undersigned declares further that all statements made herein of her own knowledge are true and that all statements made on information and belief are believe to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

MASAKAZU TAKAHASHI

Name

Masakazu Takahashi

Signature

May 1, 2007

Date